Complete Summary

GUIDELINE TITLE

Routine prenatal care.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Routine prenatal care. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jul. 74 p. [209 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES**

SCOPE

DISEASE/CONDITION(S)

Preconception and pregnancy (Counseling; Screening)

IDENTIFYING INFORMATION AND AVAILABILITY

Perinatal complications (Prevention; Risk Assessment)

GUIDELINE CATEGORY

Counseling Evaluation Prevention Risk Assessment Screening

CLINICAL SPECIALTY

Family Practice Internal Medicine Nursing Obstetrics and Gynecology Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To increase the percentage of pregnant women who receive timely, comprehensive screens for risk factors
- To increase the percentage of pregnant women who receive timely prenatal counseling and education as outlined in the guideline
- To improve the frequency of appropriate routine testing during pregnancy
- To increase the percentage of pregnant women who are up-to-date with prenatal care activities

TARGET POPULATION

All women who are pregnant or are considering pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Screening Maneuvers

- 1. Risk profiles, including preconception risk assessment, preterm labor risks, workplace/lifestyle hazards assessment, infectious disease risks, genetic risks
- 2. Screening for rubella/rubeola status
- 3. Height, weight, blood pressure, obstetric history, and physical
- 4. Breast examination, abdominal/pelvic examination, cervix check
- 5. Laboratory studies, such as cholesterol, Pap smear, ABO/Rh/antibodies, rapid plasma reagin (RPR), urine culture, hemoglobin, fetal anomaly/biochemical screening (ultrasound of nuchal translucency (NT), free beta subunit of human chorionic gonadotropin (beta-hCG), pregnancy-associated plasma protein-A (PAPP-A), chorionic villus sampling or amniocentesis if necessary), hepatitis B surface antigen, human immunodeficiency virus (HIV), group B streptococcus cultures, and gestational diabetes mellitus test
- 6. Fetal heart tones, fetal position, fundal height, obstetric ultrasound
- 7. Domestic abuse

Counseling and Education

- 1. Substance use, violence, and abuse
- 2. Nutrition and weight
- 3. Physical activity
- 4. Sexual practices

- 5. Lifestyle
- 6. Course of Care
- 7. Preterm labor prevention
- 8. Medications
- 9. Accurate recording of menstrual dates
- 10. Breastfeeding
- 11. Physiology of pregnancy, fetal growth
- 12. Body mechanics
- 13. Testing for risks in pregnancy
- 14. Lab results
- 15. Gestational diabetes mellitus
- 16. Family issues
- 17. Length of stay
- 18. Work and travel
- 19. Preregistration
- 20. Episiotomy, labor and delivery issues
- 21. Pediatric care
- 22. Warning signs in early and late pregnancy
- 23. RhoGAM
- 24. Management of late pregnancy symptoms
- 25. Contraception
- 26. Discussion of postpartum depression
- 27. Post-term management
- 28. Postpartum care
- 29. When to call a provider

Immunization and Chemoprophylaxis

- 1. Vaccinations: preconception (varicella, rubella/rubeola [measles/mumps/rubella-MMR], hepatitis B, tetanus-diphtheria [Td] booster) and post-conception (influenza)
- 2. RhoGAM D immunoglobulin
- 3. Nutritional supplements

MAJOR OUTCOMES CONSIDERED

- Cost-effectiveness of prenatal care
- Sensitivity and specificity of screening maneuvers
- Maternal/fetal health outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

No additional description of literature search strategies is available.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

Randomized, controlled trial

Class B:

Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report
- B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1-2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Ob/Gyn Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Ob/Gyn Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for routine prenatal care are presented in the form of a table with accompanying annotations. Clinical highlights and a table for routine prenatal care follow. The reader is directed to the original guideline document for further discussion of each of the following topics.

Clinical Highlights

- 1. Each pregnant patient should receive visit-specific screening tests, education, immunizations, and chemoprophylaxis as described on the prenatal flow chart (see page 1 of the original guideline document).
- 2. Each pregnant patient and each patient planning a pregnancy should receive a comprehensive risk assessment including risks for preterm labor, relevant infectious diseases, and relevant genetic disorders (Annotation #2 see original guideline document).
- 3. Providers should phase out unnecessary clinical prenatal practices including routine urine dipstick test, routine clinical pelvimetry, and universal multivitamin and iron supplementation (see "Practices to Consider Discontinuing," page 16 of the original guideline document).

Event	Preconception	Visit 1	Visit 2	Visit 3
	Visit	6 to 8 weeks	10 to 12 weeks	16 to 18
				weeks

Event	Preconception Visit	Visit 1 6 to 8 weeks	Visit 2 10 to 12 weeks	Visit 3 16 to 18
Screening Maneuvers	Risk profiles Height and weight/BMI Blood pressure Breast exam Cholesterol and HDL Pap smear Rubella/rubeola Varicella Abdominal/pelvic exam Domestic abuse screening	 Risk profiles*** Height and weight/BMI OB history and physical* Hemoglobin* Rubella/rubeola* Varicella* ABO/Rh/Ab* RPR* Urine culture* Hepatitis B surface Ag* HIV* Domestic abuse screening 	Weight Blood pressure Fetal heart tones Fetal anomaly/biochem ical screening	weeks Weight Blood pressure Fetal hea tones Fetal anomaly/ biochemic screening OB ultrasoun (optional) Fundal height
Counseling and Education	Substance use Nutrition and weight Physical activity Violence and abuse Sexual practices Preterm labor (PTL) prevention List of medications, herbal supplements, and vitamins Accurate recording of menstrual dates	** Lifestyle Nutrition Warning signs Course of care Physiology of pregnancy Testing for risks in pregnancy	Fetal growth Review lab results Breast-feeding Body mechanics	Second trimester growth Quickenir Lifestyle Physiolog of pregnanc
I mmunization and Chemoprophylaxis	Tetanus- diphtheria [Td] booster MMR Varicella Hepatitis B Nutritional supplements [High risk groups]	Tetanus-diphtheria [Td] booster Nutritional supplements [High risk groups]		

Event	Visit 5 28 weeks	Visit 6 32 weeks	Visit 7 36 weeks	Visit 8-11 38 to 41 weeks
Screening Maneuvers	Assess infectious disease risk PTL risk Weight Blood pressure Fetal heart tones Fundal height Check cervix Gestational diabetes mellitus (GDM) Domestic abuse screening Rh antibody status	Weight Blood pressure Fetal heart tones Fundal height	Weight Blood pressure Fetal heart tones Fundal height Check cervix Confirm fetal position Culture for group B streptococcus	Weight Blood pressure Fetal heart tones Fundal height Check cervix
Counseling and Education	Work Physiology of pregnancy Preregistration Fetal growth Awareness of fetal movement Preterm labor (PTL) symptoms	Travel Sexuality Pediatric care Episiotomy Labor and delivery issues Warning signs/PIH	Postpartum care Management of late pregnancy symptoms Contraception When to call provider Discussion of postpartum depression	Postpartum vaccination s Infant CPR Post-term manageme nt Labor and delivery update
Immunization and Chemoprophylaxis	ABO/Rh/Ab (RhoGAM) Influenza			

^{*}It is acceptable for the history and physical and laboratory tests listed under Visit 1 to be deferred to Visit 2 with the agreement of both the patient and the provider.

Abbreviations: CPR, cardiopulmonary resuscitation; HDL, high density lipoprotein; HIV, human immunodeficiency virus; MMR, measles/mumps/rubella; OB, obstetrics; PIH, pregnancy-induced hypertension; RPR, rapid plasma reagin

Practices To Consider Discontinuing

- Pelvimetry
- Routine urine dipsticks and routine urinalysis
- Routine evaluation for edema
- Routine testing for cytomegalovirus (CMV), parvovirus, toxoplasmosis

^{**} Should also include all subjects listed for the preconception visit if none occurred.

^{***}To be completed within 2 weeks of provider knowledge of pregnancy.

• Routine nutritional supplements

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see Supporting Evidence section, pp 32 and 33 of the original guideline document).

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and cost-effective prenatal care
- Improved maternal/fetal outcomes (reduced morbidity/mortality from obstetric complications [e.g., stillbirth, preterm delivery, chorioamnionitis, endometritis, low birth weight, and intrauterine growth restriction])

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Pocket Guide/Reference Cards Quality Measures

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NOMC MEASURES

- Routine prenatal care: percentage of pregnant women who received counseling and education by the 28th week visit.
- Routine prenatal care: percentage of prenatal activities up-to-date at the end of a prenatal visit.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Routine prenatal care. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jul. 74 p. [209 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Aug (revised 2004 Jul)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUI DELI NE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

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GUI DELI NE COMMITTEE

Ob/Gyn Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dale Akkerman, MD (Work Group Leader) (Park Nicollet Health Services) (OB/GYN); Joan Kreider, MD (HealthPartners Medical Group) (OB/GYN); John A. Jefferies, MD (Mayo Clinic) (OB/GYN); Jane Willett, DO (Affiliated Community Medical Centers (OB/GYN); Tamara Johnston, MD (Northwest Family Physicians) (Family Practice); Georgeanne Croft, CNM (HealthPartners Medical Group) (Nurse Midwifery); Amy Knox, CNM (Park Nicollet Health Services) (Nurse Midwifery); Corinne Esch, RN (HealthPartners Medical Group) (OB/GYN Nursing); Rick Carlson, MS (HealthPartners Medical Group) (Measurement Advisor); Nancy Jaeckels (Institute for Clinical Systems Improvement) (Implementation Advisor); Nancy Greer, PhD (Institute for Clinical Systems Improvement) (Evidence Analyst); Linda Setterlund, MA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform users. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously released version: Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Jul. 56 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Institute for Clinical Systems Improvement</u> (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• ICSI pocket guidelines. April 2004 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2004. 404 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 15, 2000. The information was verified by the guideline developer on March 15, 2000. This summary was updated by ECRI on April 19, 2001, May 7, 2002, February 5, 2003, March 25, 2004, and November 12, 2004.

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